

PATENT COOPERATION TREATY

From the Japan Patent Office

INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

PCT

To:

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WRITTEN OPINION

(PCT Rule 66)

Date of mailing (day/month/year) 24.06.03	
Applicant's or agent's file reference 09553	REPLY DUE within 2 months from the above date of mailing
International application No. PCT/JP03/03924	International filing date (day/month/year) 28.03.03
Priority date (day/month/year) 29.03.02	
International Patent Classification (IPC) Int. Cl ⁷ G01N33/68, G01N33/53, G01N33/15,	
Applicant Dainippon Pharmaceutical Co., Ltd.	
<p>1. This written opinion is the <u>first</u> (first, etc.) drawn up by this International Preliminary Examining Authority.</p> <p>2. This report contains indications and corresponding pages relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application <p>3. The applicant is hereby invited to reply to this opinion.</p> <p>When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).</p> <p>How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.</p> <p>Also For an additional opportunity to submit amendments, see Rule 66.4. For the examiner's obligation to consider amendments and/or argument, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6.</p> <p>If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.</p> <p>4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: <u>29.07.04</u></p>	

Name and mailing address Japan Patent Office (IPEA/JP) 4-3, Kasumigaseki 3-chome Chiyoda-ku, Tokyo 100-8915 Japan	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 5px;"> Authorized officer Examiner Shoko YAMAMURA Telephone No. 03-3581-1101 extension 3251 </td> <td style="width: 50%; padding: 5px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">2J</td> <td style="width: 50%; text-align: center;">9217</td> </tr> </table> </td> </tr> </table>	Authorized officer Examiner Shoko YAMAMURA Telephone No. 03-3581-1101 extension 3251	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">2J</td> <td style="width: 50%; text-align: center;">9217</td> </tr> </table>	2J	9217
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WRITTEN OPINION

Intern. application No. PCT/JP03/03924

I. Basis of the opinion

1. This opinion has been drawn up on the basis of (Substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed".):

☒ the international application as originally filed.

☐ the description: pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,

☐ the claims: Nos. _____, as originally filed,
Nos. _____, as amended together with any statement
under Article 19,
Nos. _____, filed with the demand,
Nos. _____, filed with the letter of _____,

☐ the drawings: pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,

☐ the sequence listing part of the description, pages _____, as originally filed,
pages _____, filed with the demand,
pages _____, filed with the letter of _____,

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language _____ which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of the international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequences disclosed in the international application, the opinion was formed on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, page _____
☐ the claims, Nos. _____
☐ the drawings, sheets/fig _____

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

WRITTEN OPINION

Intern. application No.PCT/JP03/03924

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>1-18</u>	YES
	Claims	<u></u>	NO
Inventive Step (IS)	Claims	<u></u>	YES
	Claims	<u>1-18</u>	NO
Industrial Applicability (IA)	Claims	<u>1-18</u>	YES
	Claims	<u></u>	NO

1. Citations and Explanations

Reference 1: FASEB Journal 13 (5 PART 2): pA907 March 15, 1999

Reference 2: JP 2001-037486 A (TANABE SEIYAKU Co., Ltd.) 2001.02.13

Reference 1 describes a constitution for measuring the expression of H-FABP mRNA due to adriamycin during cardiomyopathy. Reference 2 describes a constitution for measuring FABP at an mRNA level and a constitution for measuring using an anti-FABP antibody, and also describes human FABP as an FABP to be measured.

The invention of claims 1 to 18 does not have an inventive step over Reference 1 and Reference 2. Application of the method described in Reference 1 to the measurement of human H-FABP, and the constitution for measuring H-FABP using an anti-FABP antibody instead of the constitution for measuring the expression of mRNA can be easily performed by those skilled in the art.